

while 305 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective: May 15, 1996. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 15, 1996.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the act: July 16, 2002. The applicant claims July 15, 2002, as the date the new drug application (NDA) for BONIVA (NDA 21-455) was initially submitted. However, FDA records indicate that NDA 21-455 was initially submitted on July 16, 2002.

3. The date the application was approved: May 16, 2003. FDA has verified the applicant's claim that NDA 21-455 was approved on May 16, 2003.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 337 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments and ask for a redetermination by August 21, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 19, 2006. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 17, 2006.

Jane Axelrad,  
Associate Director for Policy, Center for Drug  
Evaluation and Research.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004E-0413]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; CIALIS

AGENCY: Food and Drug Administration,  
HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for CIALIS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

**ADDRESSES:** Submit written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes

effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product CIALIS (tadalafil). CIALIS is indicated for treatment of erectile dysfunction. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CIALIS (U.S. Patent No. 5,859,006) from ICOS Corporation, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 19, 2004, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of CIALIS represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for CIALIS is 1,943 days. Of this time, 1,067 days occurred during the testing phase of the regulatory review period, while 876 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* July 29, 1998. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 29, 1998.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* June 29, 2001. FDA has verified the applicant's claim that the new drug application (NDA) for CIALIS (NDA 21-368) was initially submitted on June 29, 2001.

3. *The date the application was approved:* November 21, 2003. FDA has verified the applicant's claim that NDA

21-368 was approved on November 21, 2003.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 679 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by August 21, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 19, 2006. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 17, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. 2006M-0075, 2006M-0009, 2006M-0014, 2006M-0015, 2006M-0163]

### Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

**ADDRESSES:** Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

**FOR FURTHER INFORMATION CONTACT:** Thinh Nguyen, Center for Devices and Radiological Health (HFZ-402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2186, ext. 152.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the *Federal Register* of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual

publication of PMA approvals and denials in the *Federal Register*. Instead, the agency now posts this information on the Internet on FDA's home page at <http://www.fda.gov>. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the *Federal Register*, and FDA believes that the Internet is accessible to more people than the *Federal Register*.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from January 1, 2006, through March 31, 2006. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JANUARY 1, 2006, THROUGH MARCH 31, 2006

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P020024/2006M-0075	AGA Medical Corp.	AMPLATZER DUCT OCCULUDER AND 180 DELIVERY SYSTEM	May 14, 2003
P020001/2006M-0009	Neovanta Medical AB	STAN S31 FETAL HEART MONITOR	November 1, 2005
P040001/2006M-0014	St. Francis Medical Technologies, Inc.	X STOP INTERSPINOUS PROCESS DECOMPRESSION SYSTEM	November 21, 2005
P050009/2006M-0015	Biomet, Inc.	C2 A-TAPER ACETABULAR SYSTEM	December 16, 2005